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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,718	01/08/2004	Joan M. Robbins	P-IMM 1003-2	2973

7590 09/19/2007

LAW OFFICE OF DAVID SPOLTER
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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,718	ROBBINS ET AL.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *106-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *106-139* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

Applicant's preliminary amendment to the claims, filed 8/9/2004, is acknowledged. With entry of the amendment, claims 106-139 are pending and subject to restriction as follows.

Election/Restrictions

This application contains claims directed to a plurality of related but distinct methods for treating a proliferative skin disease or scarring, comprising administering to a patient a therapeutically effective amount of a ribozyme.

The different methods are distinguished by:

I. the route of administration and the type of formulation (claims 107, 114, 115, 116, 130, 131, and 132);

II. the type of scar or proliferative skin disease (claims 108-112 and 135-139);

III. the type of ribozyme (hammerhead or hairpin) (claim 113);

IV. the type of ribonuclease inhibitor used with said ribozyme (claims 117-126); and finally

V. the nucleotide sequence of said ribozyme (claim 133).

The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

With regard to Category I, above, the methods are distinct since they require different active steps, resulting in different relative outcomes and effects in said patient. Thus, the methods of I have different designs, modes of operation, and effect. Additionally, and depending on the route of administration, the methods require different material limitations with respect to the chemical/physical characteristics of the formulation administered to said patient. For the same reasons, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

With regard to Category II, while the methods recite the same active step, the methods are directed to different patient populations, suffering from different types of scarring and skin disease. Thus, the processes of II are specific for at least two or more different patients and would result in different outcomes and effects, depending on the patient and disease treated by said method. For example, absent evidence to the contrary, a single patient would not be suffering from psoriasis, dermatitis, keratosis, basel cell carcinoma, viral disease, and seborrheic wart. Furthermore, it would be unlikely that the same patient would be suffering from keloid, adhesion, hypertrophic, and burn scars. Therefore, the different methods have different functions and effects and are designed for different patients. For the same reasons, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

With regard to Category III, the different methods require the use of structurally and functionally distinct ribozymes. Therefore, the methods are distinguished by the mutually exclusive characteristics of these ribozymes. For the same reasons, the inventions as claimed do

not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

With regard to Category IV, the methods are distinct because each method requires a materially different ribonuclease inhibitor, ranging from dithiothreitol to sodium dodecyl sulfate, from vanidyl nucleotides to RNA decoys. The methods, therefore, have different designs. As a result, each ribozyme formulation thereof would produce different relative effects and produce different relative outcomes in the target patient. For the same reasons, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

With regard to Category V, the methods require structurally distinct ribozymes, containing either SEQ ID NO:4383 or 4385. A review of these sequences indicates the sequences are distinct, one from the other. Accordingly, the ribozymes of V possess mutually exclusive characteristics, endowing each with different relative functions and/or effects. For the same reasons, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

In addition, searching and examining each of these groups in a single application would present a serious burden on the examiner, since each group would require different keyword searches (i.e., different fields of search) and different considerations of the patent and non-patent literature with regard to novelty, obviousness, written description, and enablement.

Therefore, because these inventions are distinct for the reasons given above, and the searches required for each are divergent and not coextensive, and because a search and

examination of all of the Inventions in a single application would present a serious burden on the Examiner, restriction for examination purposes as indicated is proper.

Accordingly, Applicant is required under 35 U.S.C. 121 to elect a single claimed method for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an election in each of the five categories listed above, such that, altogether, applicant elects a single, non-mutually exclusive invention for prosecution on the merits. With the election, Applicant must provide a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Linked Inventions

Applicant is advised that, although Applicant is restricted to one invention, linking claim practice is in effect.

Claim 106 link(s) the inventions of claims 107-139 (i.e., categories I-V, above). Furthermore, claim 117 is considered to be a nested linking claim, linking the inventions of claims 118-126.

The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1, the full scope of which will be examined upon a fully-responsive election.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined

for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LW

September 14, 2007

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER